

REMARKS

Reconsideration of this application is respectfully requested in view of the amendments above and following remarks. Claims 28 to 37 were pending in the present application. Following appeal under 35 USC § 134, the rejection of Claims 28, 29, and 31 to 34 under 35 USC § 102(b) over Rasmusson, and the rejection of Claims 30 and 35 to 37 under 35 USC § 103(a) over Rasmusson and Goldman were reversed. However, the Board rejected Claims 28 to 37 under a new ground of rejection. Claims 28 to 37 were rejected. Claims 28, 33, and 36 have been amended. Currently Claims 28 to 37 are pending in the present application.

Claims 28 and 33 have been amended to specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor/finasteride. The transition phrase of the claim has been changed from "comprising" to "consisting essentially of." Support for this amendment is found throughout the specification as originally filed, and particularly in Example 5, where finasteride is the sole active ingredient administered to the male test subjects.

Claim 36 has been amended to specify that the transdermal skin patch consists essentially of the 5 alpha-reductase 2 inhibitor as the active ingredient. The transition phrase of the claim has been changed from "comprising" to "consisting essentially of . . . as the active ingredient." Support for this amendment is found throughout the specification as originally filed, and particularly in Example 5, where finasteride is the sole active ingredient administered to the male test subjects.

New Ground of Rejection under 37 CFR §41.50(b)

The Board rejected Claims 28-37 under 35 U.S.C. § 103(a) as unpatentable over Goldman. The Board stated:

Goldman teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and 5- α -reductase inhibitor (column 2, lines 42-46; column 6, lines 5-9). "A highly preferred inhibitor of . . . 5- α -reductase for use in [Goldman's]

compositions and methods" (column 5, lines 43-44), indeed the only 5- α -reductase inhibitor specifically mentioned, is finasteride (column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner" (column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transdermal patches or preparation" (column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5- α -reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preferred" 5- α -reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic alopecia by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, comprising a 5- α -reductase inhibitor, e.g., finasteride, in view of Goldman's explicit suggestions.

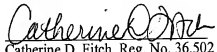
Applicants have amended Claims 28 and 33, from which Claims 29, 30, 31, 32, 34, and 35 directly or indirectly depend, to specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5 α -reductase 2 inhibitor. As the Board recognized, Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents selected from vasodilators, estradiols, 5 α -reductase inhibitors and salts, esters and prodrugs thereof. Goldman does not teach or even suggest the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5 α -reductase inhibitor. Indeed, in the only exemplification in Goldman, finasteride is used with a vasodilator and estradiol.

Applicants have amended Claim 36, from which Claim 37 depends, to specify that the transdermal skin patch "consists essentially" of a 5 α -reductase 2 inhibitor as the active ingredient. Goldman does not teach or suggest a transdermal skin patch consisting essentially of a 5 α -reductase 2 inhibitor as the active ingredient.

In view of the amendments and remarks above, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 28-37 under 35 U.S.C. § 103(a) as unpatentable over Goldman.

For the foregoing reasons, Applicants believe that with the present amendments, the instant application is in condition for allowance, or at least in better condition for appeal. If the Examiner has further questions or concerns regarding this application, she is invited to telephone the undersigned attorney at the number below.

Respectfully submitted,

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Date: January 27, 2005



Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Bill of Appeal

PATENT

Case No. 19109DE

In re application of: G.J. GORMLEY ET AL.

Serial No. 10/010,678

Filed December 7, 2001

Group Art Unit 1614

Examiner V.Y. Kim

For: TRANSDERMAL TREATMENT WITH 5-ALPHA-REDUCTASE
INHIBITORS (as amended)

Transmitted herewith is an amendment in the above-identified application.

☒ No additional fee is required.

☐ The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2) Claims remaining after amendment	(3)	(4) Highest Number Previously Paid For	(5) Present Extra	(6) Rate	(7) Additional Fee
Total Claims	* <u>10</u>	-	** <u>20</u> =	<u>0</u> X	\$50	= <u>0.00</u>
Independent Claims	* <u>3</u>	-	*** <u>3</u> =	<u>0</u> X	\$200	= <u>0.00</u>
Multiple Dependent Claims					\$360 ****	= <u> </u>
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						0.00

* If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.

** If the "Highest Number Previously Paid For" in this space is less than 20, write "20" in this space.

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**** Add this fee only if application is amended to include multiple dependent claims (regardless of number) and no multiple dependent claims were originally filed.

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MERCK & CO., INC.

By [Signature] Date 1/27/2005

Respectfully,

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IN DUPLICATE





PATENT
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